

REMARKS

Claims 39-52 and 54-58 are pending. Claims 1-32 and 34-38 were previously canceled, and claims 33 and 53 have been canceled herein. Claims 39-40, 48-49, and 51-52 have been amended. The amendments to Claim 39 merely rewrite the claim into independent form, incorporating the provisions of Claim 33, on which it formerly depended, in view of the cancellation of Claim 33. Claim 40 has been amended to depend on Claim 39 instead of now-canceled claim 33. Claims 48-49 and 51-52 have been amended merely to more particularly point out and distinctly claim the instant invention. Therefore no new matter has been added as a result of the amendments.

1. Claim Rejections – 35 USC § 112, 1st Paragraph

The Office Action has rejected claims 48-53 under 35 U.S.C. 112, 1st paragraph under the assertion that they contain subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action asserts that the limitations “for more than one day” and “for more than six days” do not appear to be disclosed within the instant application and thus are deemed new matter. Applicants respectfully traverse these assertions.

As an initial matter, Applicants have amended Claims 48-49 and 51-52 to more particular point out and distinctly claim the instant invention. Furthermore, Applicants have canceled Claim 53. With regard to pending Claims 48-52, Applicants draw the attention of the Office to pages 10-11 of the specification (“STUDY 1”). This section reports on the analysis of hyaluronidase-treated HIV infected cells in accordance with the claimed invention. As Treatments A and B exemplify, the HIV infected cells were treated with hyaluronidase for at least two days. Treatment A, for example, notes that “48 hours post infection, treatment with drugs continued for an additional 3 treatments.” As those treatments were administered every 48 hours, the cells were treated for at least 6 days (3 treatments, 48 hours apart).

Applicants also draw the attention of the Office to page 12 of the specification (“STUDY 2”) wherein HIV infected cells are treated with hyaluronidase for 48 hours, *i.e.* for at least two days.

Applicants additionally note that the Office Action has asserted that the recited phrases (“for more than one day” and “for more than six days”), now no longer recited in the claims, have support in the specification for at most 21 days. Applicants, presuming the Office Action is referring to the tables on pages 10-11, respectfully contend that the Office Action has misconstrued the teachings of “STUDY 1.” Day 21 in the tables on pages 10-11 of the specification refers to RT (reverse transcriptase) activity in the cells measured on Day 21 post-infection, not to the administration of hyaluronidase to the cells.

Based on the above, Applicants respectfully request reconsideration and withdraw of the rejection under 35 U.S.C. 112, 1st paragraph.

2. Claim Rejections – 35 USC § 112, 2nd Paragraph

The Office Action has rejected Claims 33, 39-47, and 51-53 under 35 USC 112, 2nd paragraph, under the assertion that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action asserts that there is no objective criterion or definition provided in the specification to apprise one of skill in the art of the meaning of the term “toxic concentration” recited in Claims 33 and 51. Applicants respectfully traverse these assertions.

As an initial matter, Applicants note that Claims 33 and 53 have been canceled, thus obviating their rejection. Furthermore, Applicants respectfully contend that the Office Action has applied an incorrect test for definiteness under 35 USC 112, 2nd paragraph. The test for definiteness is not whether a term is defined in the specification, or whether there are objective criteria provided in the specification. Rather, “the test for definiteness under 35 U.S.C. 112, second paragraph is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’” MPEP 2173.02, citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986).

Nevertheless, solely in order to expedite prosecution, Applicants have removed the recitation of the phrase “toxic concentration” from the claims, obviating the rejection. Applicants therefore respectfully request reconsideration and withdraw of the rejection under 35 USC 112, 2nd paragraph.

3. Claim Rejections – 35 USC § 102

The Office Action has rejected Claims 33, 40-47 and 54-58 under 35 USC 102(b) as anticipated by Guo and also as evidenced by Horwitz. Specifically, the Office Action asserts that Guo anticipates the claimed invention because Guo teaches HIV infected cells that have been treated with hyaluronidase, and that such cells would inherently have the same effect as the claimed composition when administered to a subject. Applicants respectfully traverse these assertions.

With regard to Claim 33, Applicants note that this claim has been canceled, thus obviating its rejection.

With regard to Claims 40-47, Applicants note that these claims now ultimately depend from Claim 39. As acknowledged by the Office Action, Claim 39 is not anticipated by Guo. Thus, as dependent claims necessarily incorporate the limitations of the claim from which they depend, Claims 40-47 as pending are novel in view of Guo.

With regard to Claims 54-58, Applicants respectfully contend that contrary to the assertion of the Office Action, these claims are not anticipated by Guo, either expressly or inherently. In order to anticipate a claim, a reference must teach each and every element of the claim. *MPEP 2131*. Guo teaches neither a composition “wherein the cells form HIV immunogens or antigens that prime and activate antigen presenting cells” explicitly nor a composition “wherein the HIV infected cells exhibit reduced cell viability” explicitly. As such, Applicants presume the Office Action relies on the theory of inherent anticipation in asserting that Claims 54-58 are anticipated by Guo.

Applicants respectfully contend that the Office Action has failed to establish a *prima facie* case of inherent anticipation, and that therefore the rejection is improper and must be withdrawn. “In relying upon the theory of inherency, the examiner **must** provide a basis **in fact and/or technical reasoning** to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *MPEP 2112(IV)*, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added) (reversing rejection on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency). “Inherency [] may not be established by probabilities or possibilities.” *MPEP 2112(IV)*, citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

In the instant case, the Office Action, in issuing the 102(b) rejection, has merely stated that “Guo’s same composition would also inherently have the same effect as the claimed composition when administered to a subject.” As an initial matter, the claims are not directed to methods of treatment, therefore the *effect* the compositions might have *when administered to a subject* is simply not relevant to the patentability of the pending claims. The analysis should focus instead on whether certain characteristics of the *composition* are necessarily inherently present in the prior art composition. On this matter the Office Action is silent. The Office Action has provided absolutely no objective evidence or logical technical reasoning to support its conclusion of inherency.

As such, the Office Action has failed to meet its burden in establishing a *prima facie* case of inherent anticipation, and the rejection cannot be sustained. Furthermore, even though Applicants are under no obligation to do so, they have provided evidence, in the form of a declaration of one of skill in the art (submitted with Applicant’s communication filed July 11, 2005), that the prior art composition does not necessarily or inherently possess the limitations of Claims 54-58. For the convenience of the Office, a copy of the declaration as filed is appended herewith as Exhibit A. This evidence appears to not have been considered by the Office, as it is not mentioned in the Office Action. While Applicants contend that such evidence is not required in view of the failure of the Office Action to establish a *prima facie* case of inherent anticipation, it nevertheless solidifies the patentability of Claims 54-58 over Guo.

Based on the above, Applicants respectfully request reconsideration and withdraw of the rejection under 35 USC 102(b).

CONCLUSIONS

Applicant respectfully contends that all conditions of patentability are met in the pending claims as amended and therefore respectfully request allowance.

If the Examiner believes it to be helpful, the Examiner is invited to contact the undersigned representative by telephone at (312) 913-3349.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

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